

Structured Product Labeling (SPL) OTC Sub-team Teleconference
July 12, 2010, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Joan Berger, Image Solutions, Inc.
-  Cheryl Blik, Teva Pharmaceuticals USA
-  Pam Budny, Eli Lilly
-  Iris Feliciano, Tris Pharma
-  Lisa Fields, Blistex, Inc.
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Paula Markert, GlaxoSmithKline (sub-team leader)
-  Kathryn Moreng, Bayer Consumer HealthCare
-  Kathy Olgers, Perrigo Company
-  Alison Rago, Intagras
-  Gary Saner, Reed Technology & Information Services, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Beth Thompson, Medline Industries, Inc.
-  Ann Marie Waller, Oraceutical, LLC
-  Barbara Wolfe, Pfizer Consumer Healthcare
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: August 9, 2010, 1:00pm ET (unless cancelled)

III. Discussion

A. FDA Indexing Initiative

Pam Budny, of Eli Lilly, gave a high-level overview of the indexing initiative noted in the current *Federal Register* notice (<http://edocket.access.gpo.gov/2010/pdf/2010-14047.pdf>). Although OTCs are not mentioned in the notice and it could be quite some time before indexing might apply to OTCs, potential implications and concerns/issues unique to OTCs should be considered as early in the process as possible. This is important because in some instances there may be instances where decisions made for prescription products may not appropriately apply to non-prescription products. There is currently a sub-group within the SPL Leadership Team that is developing a response to the *FR* notice. The SPL OTC sub-team working group addressing this issue will join the Leadership Team sub-group instead of working independently. The draft outline of the comments will be shared with the

full SPL OTC sub-team once they are available. SPL OTC Sub-team members should be prepared for the possibility of a short review time as comments must be submitted to the docket by August 10, 2010. A sub-team organized under the SPL Leadership Team is currently working on a proposal for an FDA public workshop to explain the initiative to stakeholders so interested parties can then provide informed feedback to the agency.

B. NLM Pillbox Initiative

The National Library of Medicine (NLM) Pillbox Initiative is a project, in conjunction with FDA, to develop a standardized approach for producing high-resolution pictures of solid oral dose medications. NLM has requested samples (minimum of 8-10, or one unit pack) for solid oral dosage forms from companies that are willing to participate in this voluntary initiative. Additional details about the program are provided as a separate attachment. Note: Companies should have any necessary discussions with their legal, manufacturing, and/or regulatory consultants prior to participation.

C. Open Discussion

1. The maximum size for the PDP jpg file is no larger than 1 MB.
2. FDA recently updated its validation procedure so the business operations listed in the establishment registration file must now match what is included in the drug listing file. Manufacturers should work with their business partners to ensure the business operations are properly noted. FDA may provide assistance on a case-by-case basis.
3. Companies are still having a few problems with importing products but not as many as before. There was a suggestion that by including the foreign manufacturer information in the SPL drug listing file may help minimize importation delays. There seems to be a question about whether foreign manufacturers must also submit a separate drug listing file so clarification will be sought from FDA.
4. Sub-team members were encouraged to send questions and concerns to Paula Markert and/or Marcia Howard to seek clarification from the appropriate agency or individual.

IV. SPL Educational Forums/Information (*For Your Information*)

- A. FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- B. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)

Telephone number: 1-866-775-9435

Participant passcode: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

NOTE: FDA Technical Q&A sessions are no longer held on Wednesdays.

Please visit the SPL Wiki page to access FDA's SPL R4 eBook Training Documents (<http://spl-work-group.wikispaces.com/>)

- C. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 517342

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

- D. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER PATRICIA L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

- E. **SPL Generics Sub-team calls:** Not currently holding regular calls.
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

F. Medical Products Sub-team calls: Every other Thursday at 10:30 am EST (starting May 6, 2010). Sub-team leader is Myron Finseth (myron.finseth@medtronic.com)

Telephone Number: 770-657-9270
Participant passcode: 745896

Please separate attachment for additional information.

MDH/07-13-10

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